Notice of Allowability	Application No.	Applicant(s)	
	08/260,536	LORENCE ET AL.	
	Examiner	Art Unit	
	Emily Le	1648	
The MAILING DATE of this communication appe All claims being allowable, PROSECUTION ON THE MERITS IS herewith (or previously mailed), a Notice of Allowance (PTOL-85) NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RI	(OR REMAINS) CLOSED in t or other appropriate commun GHTS. This application is su	his application. If not included ication will be mailed in due cours	e. THIS he initiative
1. This communication is responsive to <u>07/05/05, 11/10/05 and 11/10/0</u>	<u>d 1/04/2006</u> .		
2. The allowed claim(s) is/are <u>332-338, 342, 352, 367-374, 38</u>	86-387, 392-397, 399 and 403	3.	
<ol> <li>Acknowledgment is made of a claim for foreign priority un</li> <li>a) All b) Some* c) None of the:</li> <li>1. Certified copies of the priority documents have</li> <li>2. Certified copies of the priority documents have</li> <li>3. Copies of the certified copies of the priority documents have</li> <li>International Bureau (PCT Rule 17.2(a)).</li> </ol> * Certified copies not received:	been received. been received in Application	No	om the
Applicant has THREE MONTHS FROM THE "MAILING DATE" of noted below. Failure to timely comply will result in ABANDONM THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.		reply complying with the requiren	nents
4. A SUBSTITUTE OATH OR DECLARATION must be submi INFORMAL PATENT APPLICATION (PTO-152) which give			E OF
<ul> <li>5.  CORRECTED DRAWINGS ( as "replacement sheets") must (a)  including changes required by the Notice of Draftsperson (1)  hereto or 2)  to Paper No./Mail Date</li> <li>(b)  including changes required by the attached Examiner's Paper No./Mail Date</li> <li>Identifying indicia such as the application number (see 37 CFR 1. each sheet. Replacement sheet(s) should be labeled as such in the depose attached Examiner's comment regarding REQUIREMENT F.</li> </ul>	on's Patent Drawing Review ( Amendment / Comment or in 84(c)) should be written on the be header according to 37 CFR sit of BIOLOGICAL MATER	n the Office action of drawings in the front (not the back 1.121(d). RIAL must be submitted. Note t	
Attachment(s)  1. Notice of References Cited (PTO-892)  2. Notice of Draftperson's Patent Drawing Review (PTO-948)  3. Information Disclosure Statements (PTO-1449 or PTO/SB/06) Paper No./Mail Date (	6. Interview Sun Paper No./M	rmal Patent Application (PTO-152 nmary (PTO-413), ail Date mendment/Comment tatement of Reasons for Allowanc  James Housel Supervisory Patent Exan	e

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## Reason(s) for Allowance

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1. The broadest scope of the invention is directed at the intravenous administration of a pharmaceutical composition comprising live purified Newcastle Disease Virus, in an amount sufficient to cause tumor regression and in more than one dose, to a mammal having a tumor to treat said mammal of the tumor or cancer.

2. The above-summarized invention is free of the art. The Office is aware of the association between Newcastle Disease Virus and tumor treatments noted in the prior and present art. However, it is found that the instant invention is novel and unobvious from the teachings present in the prior art, which are included in the file history for this patent. It is found that that the prior art does not teach tumor regression in a mammal with a systemic, i.e., intravenous, administration of a pharmaceutical composition comprising live and purified Newcastle Disease Virus to said mammal. The prior art is directed at local administration, i.e., subcutaneous injection, of pharmaceutical compositions comprising attenuated Newcastle Disease Virus or unpurified Newcastle Disease Virus to influence tumor growth. Specifically, the prior art teaches the use of Newcastle Disease Virus as an adjuvant with viral oncolysates to induce an immune response against tumor antigens to inhibit tumor growth. Additionally, the art demonstrates an absence of antitumor activity with systemic administration of the virus. Moreover, the art notes that the systemic administration of the virus may actually be deleterious.

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## Conclusion

3. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Emily Le whose telephone number is (571) 272 0903. The examiner can normally be reached on Monday - Friday, 8 am - 5:30 pm.

- 4. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on (571) 272-0902. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.
- 5. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

James Housel 1906 Supervisory Patent Examiner

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